

## PATENT COOPERATION TREATY

PCT



REC'D 27 JAN 2006

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY PCT  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. <b>PCT/KR2004/002680</b>	International filing date(day/month/year) <b>19 OCTOBER 2004 (19.10.2004)</b>	Priority date (day/month/year) <b>23 OCTOBER 2003 (23.10.2003)</b>	
International Patent Classification (IPC) or national classification and IPC  <b>A61K 35/60(2006.01)i</b>			
Applicant  <b>LIM, Gap-Man</b>			

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 3 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
  - ☒ (sent to the applicant and to the International Bureau) a total of 12 sheets, as follows:
    - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
- This report contains indications relating to the following items:
  - ☒ Box No. I Basis of the report
  - ☐ Box No. II Priority
  - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Box No. IV Lack of unity of invention
  - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Box No. VI Certain documents cited
  - ☐ Box No. VII Certain defects in the international application
  - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand  <b>20 JUNE 2005 (20.06.2005)</b>	Date of completion of this report  <b>12 JANUARY 2006 (12.01.2006)</b>
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer  <b>KIM, Hee Sue</b>  Telephone No. 82-42-481-5605 

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/002680

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☒ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* 1-8, 11 received by this Authority on 09/08/2005
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- pages\* 9-10 received by this Authority on 09/08/2005
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* 12 received by this Authority on 09/08/2005
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/002680

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-6	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)**

The present invention relates to an ointment formulation for hemorrhoids prepared from the power of swellfish roe and a starfish.

The following documents have been considered for the purpose of this report:

D1 = KR 2002-64807 A1 (10. 08. 2002)

D2 = KR 2003-24512 A1 (26. 03. 2003)

D3 = KR 2001-16541 A1 (05. 03. 2001)

D1 discloses a process of preparing a therapeutic agent for hemorrhoids by heating the roe of a swellfish at a specified temperature and then mixing sodium chloride.

D2 discloses a vaginal suppository containing a mixture of treated starfish (*asterina pectinifera*).

D3 discloses an urethral detergent and a medicine for cystitis, prostatitis, and urethritis using starfish salt.

**1. Novelty**

None of the documents D1-D3 discloses the ointment for hemorrhoids comprising the power of the roe of a swellfish and a starfish.

Therefore, the subject matter of claims 1-6 is considered to be novel under PCT Article 33(2).

**2. Inventive Step**

However, there is no mention to confirm that the addition of a starfish and an additive such as banana and a *charonia sauliae* into the ointment formulation has a surprisingly changed effect on the treatment for hemorrhoids compared to the present invention. Further, the use of a starfish as a pharmaceutical agent is a simple change in materials which can be selected by a person skilled in the art, as shown in D2 and D3, and there is no remarkable difficulty in that. Therefore, the subject matter of claims 1-6 is considered to lack an inventive step under PCT Article 33(3).

**3. Industrial Applicability**

The subject matter of claims 1-6 appears to meet the requirement of PCT Article 33(4).

## DESCRIPTION

### REMEDY OINTMENT FOR PILES AND THEIR MANUFACTURING METHOD

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#### TECHNICAL FIELD

The present invention relates to a remedy ointment for piles, more particularly, to a remedy ointment for piles prepared from powder of swellfish spawn as principle ingredient for using as a treatment of internal hemorrhoids, external hemorrhoids, anal fistula and the like.

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#### BACKGROUND ART

The swellfish is, in general, considered as the most delicious food, but it can sometimes cause damage by toxin due to an inadvertent error in preparation for cookery. The reason is that the swellfish has virulence of brown liquid known as tetrodotoxin. For cooking a swellfish, therefore, a culinarian having a professional skill can only cook a swellfish. Namely, it must be demanded to give attention because a toxin of a swellfish is virulently poisonous.

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A tetrodotoxin is not decomposed at high temperature more than 300°C, and do not lose virulence in any seasoning having a severe acidity, and it is known to lose a virulence slowly in hydrochloric acid only. The above poison is more stronger 13 times than potassium cyanide(KCN) and it is known as a virulent poison such that can kill an adult having weight of 50kg on the spot by only the amount of 0.5mg.

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However, it has been tried to use the above virulent poison of a swellfish for remedy and the toxicity of a swellfish takes charge of an important role in the part of a nervous treatment in modern medical science. In other words, the

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AMENDED SHEET(ART.34)

tetrodotoxin among the toxicity of a swellfish is diluted and then the diluted tetrodotoxin has been used as an anodyne for a neuralgia, an arthritis, and a rheumatism patient, and it is known as to have sedation effect on a shock, an asthma, and a convulsions of tetanus and the like.

5 Korean Patent Application Publication No.2002-64807 that is filed by the present applicant with the Korean Patent Office disclosed a remedial agent for piles using swellfish spawn according to the known art.

The above disclosed art comprises; heat treatment and drying step which treat a spawn collected from a swellfish at 0℃ ~ 30℃ during 50 ~ 150 days;  
10 powder forming step which powder by grinding the above heat treated swellfish spawn; and mixing step forming a mixture which blend the above powder of a swellfish spawn with sodium chloride, and it further comprise a fumigating step which fumigate the above mixture using an alcohol. However, the above disclosed art has a drawback which is not only complicate for preparing process, but also the  
15 process is troublesome to use because it demand a fumigating step to treat piles.

## **DISCLOSURE OF INVENTION**

### **TECHNICAL PROBLEM**

It is an object of the present invention to provide a manufacturing method  
20 for a remedy ointment for piles which can be easily prepared and is simultaneously convenient to use and easy to store because of preparation in the form of ointment-type. It is also an object of the present invention to provide a remedy ointment for piles produced by the above process.

### **TECHNICAL SOLUTION**

25 In order to achieve the above object, the present invention provides a remedy ointment for piles and a manufacturing method for the same, in which a

AMENDED SHEET(ART.34)

manufacturing method for a remedy ointment for piles is technical gist of comprising following steps; forming a base-mixture which consist of collecting an spawn of a swellfish and a starfish and powdering the same; forming a mixture which is obtained by mixing the powder of a starfish and a swellfish spawn  
5 obtained by the above step with a mixture of banana, salt, and water; mixing an alcohol in the a vessel contained the mixture formed by the above step; mixing at heating state which consist of heating the vessel filled with the alcohol-mixture obtained by the above step, firing the alcohol in the vessel by indirect transmission of heat and remixing at the fired state; and, cooling the mixture at the normal  
10 temperature by natural cooling.

The present invention provides also as technical gist a remedy ointment for piles which is prepared by step of forming a powder from an spawn of a swellfish and a starfish, forming a mixture by mixing the above powder with a mixture of banana, salt, and water in a vessel, mixing an alcohol in the above vessel; mixing  
15 at heating state which consist of heating the vessel filled with the alcohol-mixture, firing the alcohol in the vessel by indirect transmission of heat and remixing at the fired state, and then cooling the mixture at the normal temperature.

Wherein, the above spawn of a swellfish and a starfish are dried by heat-treatment at 0℃~30℃ during 50~ 150 days and grinded to form powder, and the  
20 mixing ratio by weight of swellfish spawn : starfish : banana : salt : water for the above mixture is preferably in the range of 1 : 0.1~0.5 : 10~20 : 0.05~0.1 : 2~5, it is more preferable that a powder of a charonia sauliae is further included to the above mixture.

According to the above described present invention, the remedy ointment  
25 for piles has an advantage that it can be easily prepared and is simultaneously convenient to use and easy to store because of preparation in the form of ointment-type, and has prominent effect in treatment of a piles.

AMENDED SHEET(ART.34)

The preferred embodiments of the present invention is best understood with reference to the accompanying drawings, wherein:

Figure 1 is a flowchart presenting a preparing process according to the present invention.

5 As shown at a figure, the preparing process of a remedy ointment for piles according to the present invention consists of a step forming a base-mixture; a step forming a mixture; a step mixing an alcohol; a step mixing at heating state; and, a step cooling the mixture.

First, it is explained in detail on the step forming a base-mixture.

10 The above step forming a base-mixture is a step of preparing a powder of a swellfish spawn and a starfish.

A powder of a swellfish spawn is prepared by using a swellfish spawn containing a tetrotoxin.

15 Before everything, a swellfish spawn is collected from a swellfish. At this time, the swellfish that can be used is preferably *Lagocephalus lunaris spadiceus*, *Takifugu xanthopterus*, *Tetraodonitidae*, *Lagocephalus lunaris* and the like, in the aspect of efficacy, *Tetraodonitidae* is most preferable and a swellfish spawn is collected in the aggregated state each other.

20 The collected swellfish spawn is subjected a drying process by heat treatment, the above drying process by heat treatment continued at a temperature of 0°C ~ 30°C during from 50 days to 150 days.

It is not also harmful even though the above drying process by heat treatment is processed in a shadow at normal temperature.

25 Provided a swellfish spawn in the aggregated state each other is subjected the above drying process by heat treatment, the moisture contained in a swellfish spawn is entirely removed.

AMENDED SHEET(ART.34)

Wherein the present invention, the reason of executing the above drying process at low or normal temperature is to prevent a breakup of a mass of a swellfish spawn and to prevent a lose of a toxicity contained in a swellfish spawn.

In the process of powdering a swellfish spawn subjected the above drying process, it can be grinded to powder by giving a prescribed impact using a hammer made of rubber. Wherein, the above swellfish spawn can be allowed to disaggregate a unit of granule.

The above powder of a starfish is also prepared the starfish containing a tetrotoxin. A starfish is allowed to dry at a temperature of  $0^{\circ}\text{C} \sim 30^{\circ}\text{C}$  during from about 50 days to about 150 days. And then the dried starfish is allowed to be grinded to powder by giving a prescribed impact to it using a hammer.

Even though we explained in the above a process drying a swellfish spawn and a starfish and then powdering the same, it is not also harmful to powder by the milling method using mixer etc. at the state of not drying a swellfish spawn and a starfish and this method is also included the scope of the present invention.

With completion of the above procedure, the preparing powder of a swellfish spawn and a starfish is accomplished.

Next, a step forming mixture is followed. At this step, the powder of a swellfish spawn and a starfish prepared by the above step forming a base-mixture is introduced into a vessel, and a certain amount of banana, salt, and water is also introduced to the above vessel, and then the content in the vessel is mixed each other. The above banana is known as good food for constipation or piles and has strong effect as enema. And the above salt plays a role as disinfecting and contracting the diseased part and promoting the circulation of the blood.

If necessary, a powder of a charonia sauliae can be further included to the above mixture with a desired amount. At this time, the mixing ratio by weight of

AMENDED SHEET(ART.34)



swellfish spawn : starfish : banana : salt : water : charonia sauliae for the above mixture is in the range of 1 : 0.1~0.5 : 10~20 : 0.05~0.1 : 2~5 : 0.1~0.5. The above charonia sauliae is big as grown up to 30cm and carnivorous that lives on an echinoderm such as starfish and sea slug. And the above charonia sauliae is  
5 a natural enemy of starfish which is main material of the present invention.  
That is, the present invention characterizes a remedy ointment for piles whose main materials are an spawn of swellfish having tetrodotoxin and a starfish. And the charonia sauliae is a natural enemy of the starfish that the  
tetrodotoxin in the starfish is accumulated in the charonia sauliae. Therefore,  
10 using of the charonia sauliae maximize the efficacy of the remedy ointment for piles by increasing the tetrodotoxin content.

With completion of the above procedure forming mixture, the step mixing alcohol is followed. At this step, a certain amount of alcohol is added to the vessel received the above mixture, and then the content in the vessel is mixed each other.

15 Next, a step mixing at heating state is followed. This step is proceeded the way that the mixture received in the vessel, mixed with alcohol, is heated with indirect heat transmission way.

Provided that the above mixture is heated, alcohol is fired, and then at fired state the mixture mixed within the vessel is remixed with agitation. The ignited fire  
20 is maintained a fired state till alcohol is entirely consumed. With consumption of alcohol, the fire is out.

With completion of a step mixing at heating state by the above procedure, the cooling step is followed. This cooling step proceeded the way that cool at normal temperature by natural cooling.

25 With completion of the above cooling step, the remedy ointment for piles according to the present invention is obtained in the form of ointment having hard gel state.

AMENDED SHEET (ART. 34)

The remedy ointment for piles obtained by the above procedure can be used by the way that put it on piles and anal fistula and the like.

### **ADVANTAGEOUS EFFECTS**

5           The remedy ointment for piles according to the present invention obtained by the above procedure can be easily prepared and is simultaneously convenient to use and easy to store because of preparation in the form of ointment-type.

### **DESCRIPTION OF DRAWINGS**

10           Other objects and aspects of the present invention will become apparent from the following description of embodiments with reference to the accompanying drawing in which:

Figure 1 is a flowchart presenting a preparing process of the remedy ointment for piles according to the present invention.

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### **BEST MODE**

The manufacturing method for a remedy ointment for piles according to the present invention is preferably constructed comprising following steps; forming a base-mixture which consist of collecting an spawn of a swellfish and a starfish and  
20   powdering the same; forming a mixture which is obtained by mixing the powder of a starfish and a swellfish spawn obtained by the above step with a mixture of banana, salt, and water; mixing an alcohol in the a vessel contained the mixture formed by the above step; mixing at heating state which consist of heating the vessel filled with the alcohol-mixture obtained by the above step, firing the alcohol  
25   in the vessel by indirect transmission of heat and remixing at the fired state; and, cooling the mixture at the normal temperature by natural cooling.

The above step forming a base-mixture can be executed in the way that

AMENDED SHEET (ART. 34)

spawn of a swellfish and a starfish are dried by heat-treatment at 0°C~30°C during 50~ 150 days and grinded to form powder, and the mixing ratio by weight of swellfish spawn : starfish : banana : salt : water for the above mixture is preferably in the range of 1 : 0.1~0.5 : 10~20 : 0.05~0.1 : 2~5, a powder of a charonia sauliae  
5 is also further included at the step forming mixture.

The remedy ointment for piles prepared by the above manufacturing method can be formed such that a spawn of a swellfish and a starfish are dried and pulverized, then it is introduced into a vessel and banana, salt, and water are added to the vessel to form a mixture, and alcohol is mixed in the above vessel,  
10 and the mixture is remixed at the fired state by ignition of alcohol by indirect transmission of heat, and then the mixture is cooled at the normal temperature, it is possible to further include a charonia sauliae to the above mixture.

## CLAIMS

1. A method for manufacturing a remedy ointment for piles comprising the steps of; forming a base-mixture which consist of collecting an spawn of a swellfish and a starfish and powdering the same; forming a mixture  
5 which is obtained by mixing the powder of a starfish and a swellfish spawn obtained by the above step with a mixture of banana, salt, and water; mixing an alcohol in the a vessel contained the mixture formed by the above step; mixing at heating state which consist of heating the vessel filled with the alcohol-mixture  
10 obtained by the above step, firing the alcohol in the vessel by indirect transmission of heat and remixing at the fired state; and, cooling the mixture at the normal temperature by natural cooling.

2. The method according to claim 1, wherein said step forming a  
15 base-mixture be executed in the way that spawn of a swellfish and a starfish are dried by heat-treatment at 0°C~30°C during 50~ 150 days.

3. The method according to claim 1 or 2, wherein the mixing ratio by weight of swellfish spawn : starfish : banana : salt : water for the said mixture is in  
20 the range of 1 : 0.1~0.5 : 10~20 : 0.05~0.1 : 2~5.

4. The method according to claim 3, wherein, at said step forming a mixture, powder of a charonia sauliae is further included.

25 5. The remedy ointment for piles that is prepared by drying and pulverizing an spawn of a swellfish and a starfish, then introducing into a vessel, adding banana, salt, and water to the vessel to form a mixture, mixing alcohol in

AMENDED SHEET(ART.34)

the above vessel, remixing the mixture at the fired state by ignition of alcohol by indirect transmission of heat, and then cooling the mixture at the normal temperature.

- 5            6.        The remedy ointment for piles according to claim 5, wherein further include a charonia sauliae to the above mixture.

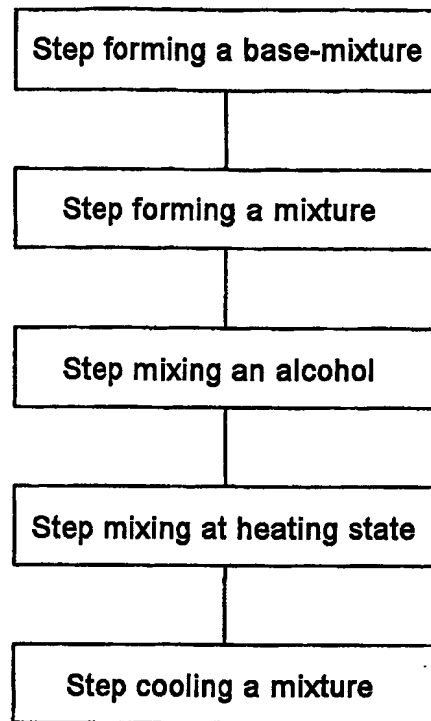
AMENDED SHEET(ART.34)

## ABSTRACT

The present invention relates to a remedy ointment for piles, in which the remedy ointment for piles and their manufacturing method are technical gist of comprising following steps; forming a base-mixture which consist of collecting an spawn of a swellfish and a starfish and powdering the same; forming a mixture  
5 which is obtained by mixing the powder of a starfish and a swellfish spawn obtained by the above step with a mixture of banana, salt, and water; mixing an alcohol in the a vessel contained the mixture formed by the above step; mixing at heating state which consist of heating the vessel filled with the alcohol-mixture  
10 obtained by the above step, firing the alcohol in the vessel by indirect transmission of heat and remixing at the fired state; and, cooling the mixture at the normal temperature by natural cooling. According to the present invention, the above remedy ointment for piles has an advantage that it can be easily prepared and is simultaneously convenient to use and easy to store because of preparation in the  
15 form of ointment-type, and has prominent effect in treatment of piles.

AMENDED SHEET(ART.34)

FIG. 1



AMENDED SHEET(ART.34)